



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,320	02/06/2004	Kevin S. Marchitto	D6327CIP	8525

7590 08/17/2010
Benjamin Aaron Adler
ADLER & ASSOCIATES
8011 Candle Lane
Houston, TX 77071

EXAMINER

MOORE, SUSANNA

ART UNIT	PAPER NUMBER
----------	--------------

1624

MAIL DATE	DELIVERY MODE
-----------	---------------

08/17/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/774,320	Applicant(s) MARCHITTO ET AL.	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/30/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-19 and 21-50 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 18, 26, 29, 30 and 40-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8, 9, 12-19, 21-25, 27, 28 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 9/23/2009 is acknowledged. Group I, drawn to a composition comprising a biomolecule and a metal susceptor, embraced by claims 1-9, 12-19 and 21-30 was elected by Applicant. Applicant has not pointed to any errors in the Examiner's analysis of the classification of the different inventions. The requirement is still deemed proper and is therefore made **FINAL**.

Applicant has chosen albumin protein as the biomolecule, titanium alloy as the metal susceptor, radiofrequency as the electromagnetic energy, conformation change as the biochemical reaction specie, chemical bond involving dimer as the bond specie and tissue as the location. Applicant states the claims which read upon each specie election. This is not correct. Applicant should have only elected all the claims which read upon the species elected. Thus, claims 1-5, 8, 9, 12-17, 19, 21-25, 27, 28 and 31-39 are currently under consideration.

There are 47 claims pending and 29 under consideration. Claims 6, 7, 18, 26, 29, 30 and 40-50 are claims drawn to a nonelected subject matter, which are currently withdrawn from consideration. This is the first action on the merits. The application concerns a composition comprising a biomolecule and a metal susceptor.

Specification

The disclosure is objected to because of the following informalities: The first paragraph in the Specification should indicate up-to-date claims of benefit to priority U.S. Applications. Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11. Appropriate correction is required.

Claim Objections

This application contains claims 6, 7, 18, 26, 29, 30 and 40-50, drawn to an invention nonelected without traverse in the paper of 9/30/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claims 9 and 32 are objected to because of the following informalities: claims 9 and 32 are not further limiting claims 1 and 24, respectively. Appropriate correction is required.

Claim 24 is objected to because of the following informalities: claim 24 is the same in scope as claim 1, since the intended use of claim 1 is not given patentable weight. Appropriate correction is required.

Claims 16 and 34 are objected to because of the following informalities: stainless steel was elected and titanium has been removed by amendment. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 9, 12-17, 19, 21, 22, 24, 25, 27, 28 and 31-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Klinger et. al. (J. Biomed. Mat. Res., 1998, 36(3), pages 387-393).

The references teaches albumin and a titanium alloy in a composition, see page 388, the Profile of HAS adsorption to Ti powder. The titanium alloy was characterized as titanium

Art Unit: 1624

dioxide, see page 388, Ti powder. Most if not all titanium sold commercially is sold as an alloy.

The optical density of the samples was measured at 595 nm, see page 388, Protein assay.

Titanium can bind more than one albumin and binds on the albumin at multiple sites. Claims 12-14, 19-22 and 35-37 are inherent properties of the titanium or bound titanium to albumin either before, during or after the exposure to a radiofrequency.

Thus, said claims are anticipated by Klinger et. al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nomoto et. al. (US 20030113368).

The instant invention claims compositions comprising a biomolecule, a metal susceptor and a pharmaceutical incorporated into a liposome.

The reference teaches compositions comprising albumin (biomolecule, see page 11, paragraph 0126), titanium (a metal susceptor, see the 9th line from the bottom of the right-hand column on page 4) and estrogen (a pharmaceutical, see page 5, paragraph 0046) in a liposome, see the abstract on the face page. The reference teaches said liposomes as a structure that has both drug holding capabilities and sustained release properties.

Thus, it would have been obvious to make a composition of albumin, a titanium alloy and a pharmaceutical, e.g. estrogen, and incorporate it into a liposome as shown by Nomoto et. al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624